

## NOTICES OF EXEMPT RULEMAKING

The Administrative Procedure Act requires the *Register* publication of the rules adopted by the state's agencies under an exemption from all or part of the Administrative Procedure Act. Some of these rules are exempted by A.R.S. §§ 41-1005 or 41-1057; other rules are exempted by other statutes; rules of the Corporation Commission are exempt from Attorney General review pursuant to a court decision as determined by the Corporation Commission.

### NOTICE OF FINAL EXEMPT RULEMAKING

#### TITLE 9. HEALTH SERVICES

#### CHAPTER 10. DEPARTMENT OF HEALTH SERVICES HEALTH CARE INSTITUTIONS: LICENSING

*Editor's Note: The following Notice of Final Exempt Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 475.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 16, 2012.*

[R14-13]

#### PREAMBLE

- | <u>1. Article, Part or Sections Affected (as applicable)</u> | <u>Rulemaking Action</u> |
|--|--------------------------|
| R9-10-1501   | Amend                    |
| R9-10-1502   | Amend                    |
| R9-10-1503   | Amend                    |
| R9-10-1504   | Amend                    |
| R9-10-1505   | Amend                    |
| R9-10-1506   | Amend                    |
| R9-10-1507   | Amend                    |
| R9-10-1508   | Amend                    |
| R9-10-1509   | Amend                    |
| R9-10-1510   | Amend                    |
| R9-10-1511   | Amend                    |
| R9-10-1512   | Amend                    |
| R9-10-1513   | Amend                    |
| R9-10-1514   | Amend                    |
| R9-10-1515   | New Section              |
- 2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific) and the statute or session law authorizing the exemption:**
- Authorizing statutes: A.R.S. § 36-136(F)
- Implementing statutes: A.R.S. §§ 36-132(A)(17), 36-405, 36-449.01 through 36-449.03, 36-2151 through 36-2153, 36-2156, 36-2158, and 36-2159
- Statute or session law authorizing the exemption: Laws 2012, Ch. 250, § 10
- 3. The effective date of the rule and the agency's reason it selected the effective date:**
- April 1, 2014
- This date will provide abortion clinics with over two months after the date of filing for the abortion clinics to implement changes required by the rules.
- 4. A list of all notices published in the *Register* as specified in R9-1-409(A) that pertain to the record of the exempt rulemaking:**
- Notice of Public Information: 19 A.A.R. 3944, November 29, 2013
- 5. The agency's contact person who can answer questions about the rulemaking:**
- Name: Kathryn McCanna, Branch Chief
- Address: Department of Health Services  
Division of Licensing Services  
150 N. 18th Ave., Suite 405  
Phoenix, AZ 85007

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Telephone: (602) 364-2536  
Fax: (602) 364-4764  
E-mail: Kathryn.McCanna@azdhs.gov  
or  
Name: Robert Lane, Acting Manager  
Address: Department of Health Services  
Office of Administrative Counsel and Rules  
1740 W. Adams, Suite 203  
Phoenix, AZ 85007  
Telephone: (602) 542-1020  
Fax: (602) 364-1150  
E-mail: Robert.Lane@azdhs.gov

**6. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered to include an explanation about the rulemaking:**

Arizona Revised Statutes (A.R.S.) §§ 36-132(A)(17) and 36-405 authorize the Department to license and regulate health care institutions, including abortion clinics. The Department has implemented A.R.S. §§ 36-132(A)(17) and 36-405 for abortion clinics in Arizona Administrative Code (A.A.C.) Title 9, Chapter 10, Article 15. On April 12, 2012, the Governor signed HB 2036, which changed requirements for abortion clinics. HB 2036 was effective August 2, 2012. HB 2036 gives the Arizona Department of Health Services (Department) exempt rulemaking authority to amend the rules for abortion clinics. After receiving an exception from the Governor's rulemaking moratorium, established by Executive Order 2012-03, for this rulemaking, the Department has revised the rules in 9 A.A.C. 10, Article 15 to delete unnecessary and obsolete provisions, address technical changes, and comply with the statutory changes. All changes conform to current rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

**7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**

None

**8. A showing of good cause why the rule is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable

**9. The summary of the economic, small business, and consumer impact, if applicable:**

Not applicable

**10. A description of any changes between the proposed rulemaking, including any supplemental proposed rulemaking, and final rulemaking package, (if applicable):**

Not applicable

**11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments, if applicable:**

Not applicable

**12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules. When applicable, matters shall include, but not be limited to:**

**a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:**

The rule does not require a permit.

**b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than the federal law and if so, citation to the statutory authority to exceed the requirements of the federal law:**

Not applicable

**c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:**

Not applicable

**13. A list of any incorporated by reference material and its location in the rules:**

None

**14. Whether this rule previously made, amended, repealed or renumbered as an emergency rule. If so, the agency shall**

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**state where the text changed between the emergency and the exempt rulemaking packages:**

The rule was not previously made, amended, repealed, or renumbered as an emergency rule.

**15. The full text of the rules follows:**

**TITLE 9. HEALTH SERVICES**

**CHAPTER 10. DEPARTMENT OF HEALTH SERVICES  
HEALTH CARE INSTITUTIONS: LICENSING**

**ARTICLE 15. ABORTION CLINICS**

Section

- R9-10-1501. Definitions
- R9-10-1502. Application Requirements
- R9-10-1503. Administration
- R9-10-1504. Incident Reporting
- R9-10-1505. Personnel Qualifications
- R9-10-1506. Staffing Requirements
- R9-10-1507. Patient Rights
- R9-10-1508. Abortion Procedures
- R9-10-1509. Patient Transfer and Discharge
- R9-10-1510. Medications and Controlled Substances
- R9-10-1511. Medical Records
- R9-10-1512. Environmental and Safety Standards
- R9-10-1513. Equipment Standards
- R9-10-1514. Physical Facilities
- R9-10-1515. Enforcement

**ARTICLE 15. ABORTION CLINICS**

**R9-10-1501. Definitions**

In addition to the definitions in A.R.S. §§ 36-401, 36-449.01, 36-449.03, and R9-10-101, the following definitions apply in this Article, unless the context otherwise requires specified:

1. *"Abortion" means the use of a surgical instrument or a machine with the intent to terminate a woman's pregnancy for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, to terminate an ectopic pregnancy or to remove a dead fetus. Abortion does not include birth control devices or oral contraceptives.*
2. *"Abortion clinic" means a facility, other than an accredited hospital, in which five or more first trimester abortions in any month or any second or third trimester abortions are performed.*
- 3-1. "Admission" means documented acceptance by a hospital of an individual as an inpatient as defined in R9-10-201 on the order of a physician.
- 4-2. "Admitting privileges" means permission extended by a hospital to a physician to allow admission of a patient:
  - a. By the patient's own physician, or
  - b. Through a written agreement between the patient's physician and another physician that states that the other physician has permission to personally admit the patient to a hospital in this state and agrees to do so.
5. ~~"Adverse reaction" means an unexpected occurrence that threatens the health and safety of a patient.~~
6. ~~"Biohazardous medical waste" means cultures and stocks, waste human blood and blood products, bodily fluids, uterine contents, and discarded medical sharps.~~
- 7-3. "Conspicuously posted" means placed at a location within an abortion clinic that is accessible and visible to patients and the public.
8. ~~"Controlled substance" means the same as defined in A.R.S. § 32-1901(12).~~
- 9-4. "Course" means hands-on practice under the supervision of a physician, training, or education.
10. "Current" means up to date, extending to the present time.
11. ~~"Department" means the same as defined in A.R.S. § 36-401.~~
12. ~~"Direction" means the same as defined in A.R.S. § 36-401.~~
- 13-5. "Discharge" means a patient no longer requires the medical services, nursing services, or health-related services provided by the abortion clinic.
14. ~~"Documentation" means written, supportive evidence.~~

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- ~~15.6.~~“Emergency” means a potentially life-threatening occurrence that requires an immediate response or medical treatment.
- ~~16.7.~~“Employee” means an individual who receives compensation from a licensee, but does not provide medical services, nursing services, or health-related services.
- ~~17.~~ “*Fetus*” means an individual human organism from fertilization until birth.
- ~~18.8.~~“First trimester” means 1 through 14 weeks as measured from the first day of the last menstrual period or 1 through 12 weeks as measured from the date of fertilization.
- ~~19.~~ “Gestational age” means the number of completed weeks of the unborn fetus as calculated from the first day of the last menstrual period or the date of fertilization.
- ~~20.~~ “Health-related services” means the same as defined in A.R.S. § 36-401.
- ~~21.~~ “Immediately” means without delay.
- ~~22.9.~~“Incident” means an abortion related patient death or serious injury to a patient or viable fetus.
- ~~23.~~ “Infection control” means to identify, prevent, monitor, and minimize infections.
- ~~24.10.~~“Licensee” means an individual, a partnership, an association, a limited liability company, or corporation authorized by the Department to operate an abortion clinic.
- ~~25.11.~~“Local” means under the jurisdiction of a city or county in Arizona.
- ~~26.12.~~“Medical director” means a physician who is responsible for the direction of the medical services, nursing services, and health-related services provided to patients at an abortion clinic.
- ~~27.13.~~“Medical evaluation” means obtaining a patient's medical history, performing a physical examination of a patient's body, and conducting laboratory tests as provided in R9-10-1508.
- ~~28.~~ “Medical services” means the same as defined in A.R.S. § 36-401.
- ~~29.~~ “Medication” means a prescription medication as defined in A.R.S. § 32-1901 or a nonprescription drug or over-the-counter drug as defined in A.R.S. § 32-1901.
- ~~30.14.~~“Monitor” means to observe and document, continuously or intermittently, the values of certain physiologic variables on a patient such as pulse, blood pressure, oxygen saturation, respiration, and blood loss.
- ~~31.15.~~“Nationally recognized medical journal” means any publication distributed nationally that contains peer-reviewed medical information, such as the *American Journal of Radiology* or the *Journal of Ultrasound in Medicine*.
- ~~32.~~ “Nurse” means an individual licensed and in good standing as a registered nurse or a practical nurse according to A.R.S. Title 32, Chapter 15.
- ~~33.~~ “Nurse practitioner” means an individual licensed and in good standing as a registered nurse practitioner according to A.R.S. Title 32, Chapter 15.
- ~~34.~~ “Nursing services” means the same as defined in A.R.S. § 36-401.
- ~~35.16.~~“Patient” means a female receiving medical services, nursing services, or health-related services related to an abortion.
- ~~36.17.~~“Patient care staff” means a physician, registered nurse practitioner, nurse, physician assistant, or surgical assistant who provides medical services, nursing services, or health-related services to a patient.
- ~~37.18.~~“Patient Patient’s representative” means a patient's legal guardian, an individual acting on behalf of a patient with the written consent of the patient, or a surrogate according to A.R.S. § 36-3201(~~13~~).
- ~~38.19.~~“Patient transfer” means relocating a patient requiring medical services from an abortion clinic to another health care institution.
- ~~39.20.~~“Personally identifiable patient information” means:
- The name, address, telephone number, e-mail address, Social Security number, and birth date of:
    - The patient,
    - The patient’s representative,
    - The patient’s emergency contact,
    - The patient’s children,
    - The patient’s spouse,
    - The patient’s sexual partner, and
    - Any other individual identified in the patient’s medical record other than patient care staff;
  - The patient’s place of employment;
  - The patient’s referring physician;
  - The patient’s insurance carrier or account;
  - Any “individually identifiable health information” as proscribed in 45 CFR 164-514; and
  - Any other information in the patient’s medical record that could reasonably lead to the identification of the patient.
- ~~40.21.~~“Personnel” means patient care staff, employees, and volunteers.
- ~~41.22.~~“Physical facilities” means property that is:
- Designated on an application for a license by the applicant; and
  - Licensed to provide services by the Department according to A.R.S. Title 36, Chapter 4.

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- 42. "Physician" means an individual licensed according to A.R.S. Title 32, Chapter 13 or 17.
- 43. "Physician assistant" means an individual licensed according to A.R.S. Title 32, Chapter 25.
- 44. ~~"Serious injury" means an injury that occurs at an abortion clinic and that creates a serious risk of substantial impairment of a major body organ.~~
- 45. ~~"Supervision" means direct overseeing and inspection of the act of accomplishing a function or activity.~~
- 46.23. "Surgical assistant" means an individual who is not licensed as a physician, physician assistant, registered nurse practitioner, or nurse who performs duties as directed by a physician, physician assistant, registered nurse practitioner or nurse.
- 47. ~~"Viable fetus" means the same as defined in A.R.S. § 36-2301.01.~~
- 48.24. "Volunteer" means an individual who, without compensation, performs duties as directed by a member of the patient care staff at an abortion clinic.

**R9-10-1502. Application Requirements**

An applicant shall submit an application for licensure that meets the requirements in A.R.S. § 36-422 and 9 A.A.C. 10, Article 1.

**R9-10-1503. Administration**

- A. A licensee is responsible for the organization and management of an abortion clinic.
- B. A licensee shall:
  - 1. ~~Ensure compliance with federal and state laws, rules, and local ordinances;~~
  - 2.1. Adopt policies and procedures for the administration and operation of an abortion clinic;
  - 3.2. Designate a medical director who is licensed according to A.R.S. Title 32, Chapter 13, 17, or 29. The licensee and the medical director may be the same individual;
  - 4.3. Ensure that the Department's director or director's designee representative is allowed access as follows:
    - a. For a complaint inspection, upon presentation of an administrative search warrant authorizing the inspection of the abortion clinic; or
    - b. For a licensing or compliance inspection, at a date and time agreed to by the licensee and the Department that is no later than 10 business days after the date the Department submits a written request to the licensee to schedule the licensing or compliance inspection, unless the Department agrees to a later date and time;
  - 5.4. Ensure the following documents are conspicuously posted at the physical facilities:
    - a. Current abortion clinic license issued by the Department;
    - b. Current telephone number and address of the unit in the Department's Office of Medical Facilities Department responsible for licensing the abortion clinic;
    - c. Evacuation map; and
    - d. Signs that comply with A.R.S. § 36-2153(G).
- C. A medical director shall ensure written policies and procedures are ~~developed~~ established, documented, and implemented for:
  - 1. Personnel qualifications, duties, and responsibilities;
  - 2. Individuals qualified to provide counseling in the abortion clinic and the amount and type of training required for an individual to provide counseling;
  - 3. Verification of the competency of the physician performing an abortion according to R9-10-1505;
  - 4. The storage, administration, accessibility, disposal, and documentation of a medication, and a controlled substance;
  - 5. Accessibility and security of patient medical records;
  - 6. Abortion procedures including recovery and follow-up care; and the minimum length of time a patient remains in the recovery room or area based on:
    - a. The type of abortion performed;
    - b. The estimated gestational age of the fetus;
    - c. The type and amount of medication administered; and
    - d. The physiologic signs including vital signs and blood loss;
  - 7. Infection control including methods of sterilizing equipment and supplies;
  - 8. Medical emergencies; and
  - 9. Patient discharge and patient transfer.

**R9-10-1504. Incident Reporting**

- A. A licensee shall ensure that the Department is notified of an incident as follows:
  - 1. For the death of a patient, verbal notification the next working day; and
  - 2. For a serious injury, written notification within 10 calendar days ~~from~~ after the date of the serious injury.
- B. A medical director shall conduct an investigation of an incident and ~~develop a written document an~~ incident report that includes:
  - 1. The date and time of the incident;
  - 2. The name of the patient;

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3. ~~Description~~ A description of the incident;
  4. Names of individuals who observed the incident;
  5. Action taken by patient care staff and employees during the incident ~~or~~ and immediately following the incident; and
  6. Action taken by the patient care staff and employees to prevent the incident from occurring in the future.
- C. A medical director shall ensure that the ~~written~~ incident report is:
1. Submitted to the Department and, ~~if the incident involved a licensed individual, the applicable~~ a professional licensing board, ~~if applicable,~~ within 10 calendar days ~~from~~ after the date of the notification in subsection (A); and
  2. Maintained in the physical facilities for at least two years ~~from~~ after the date of the ~~report~~ incident.

**R9-10-1505. Personnel Qualifications and Records**

A licensee shall ensure that:

1. A physician who performs an abortion demonstrates to the medical director that the physician is competent to perform an abortion by:
  - a. The submission of documentation of education and experience; and
  - b. Observation by or interaction with the medical director;
2. Surgical assistants and volunteers who provide counseling and patient advocacy receive training in these specific responsibilities and any other responsibilities assigned and that documentation is maintained in the individual's personnel file of the training received;
3. An individual who performs an ultrasound provides documentation that the individual is:
  - a. A physician;
  - b. A physician assistant, registered nurse practitioner, or nurse who completed a hands-on course in performing ultrasounds under the supervision of a physician; or
  - c. An individual who:
    - i. Completed a hands-on course in performing ultrasounds under the supervision of a physician, and
    - ii. Is not otherwise precluded by law from performing an ultrasound;
4. An individual has completed a course for the type of ultrasound the individual performs;
5. A personnel file for each member of the patient care staff and each volunteer is maintained either electronically or in writing and includes:
  - a. The individual's name; ~~and~~ position title; ~~and~~
  - b. ~~the~~ The first and, ~~if applicable, the~~ last date of employment or volunteer service; ~~if applicable;~~
  - b. Verification of qualifications, training, or licensure, ~~if as~~ as applicable;
  - c. Documentation of cardiopulmonary resuscitation certification, ~~if as~~ as applicable;
  - d. Documentation of verification of competency, as required in subsection (1), and signed and dated by the medical director;
  - e. Documentation of training for surgical assistants and volunteers; and
  - f. Documentation of completion of a course as required in subsection (3), for an individual performing ultrasounds; and
6. Personnel files are maintained in the physical facilities for at least two years from the ending date of employment or volunteer service.

**R9-10-1506. Staffing Requirements**

A. A licensee shall ensure that there ~~are~~ is a sufficient number of patient care staff and employees to:

1. Meet the requirements of this Article;
2. Ensure the health and safety of a patient; and
3. Meet the needs of a patient based on the patient's medical evaluation.

B. A licensee shall ensure that:

1. A member of the patient care staff, except for a surgical assistant, who is current in cardiopulmonary resuscitation certification is in the physical facilities until all patients are discharged;
2. A physician, with admitting privileges at ~~an accredited hospital in this state~~ a health care institution that is classified by the director as a hospital according to A.R.S. § 36-405(B), remains on the premises of the abortion clinic until all patients who received a medication abortion are stable and ready to leave ~~the recovery room; and~~
3. A physician, with admitting privileges at a health care institution that is classified by the director as a hospital according to A.R.S. § 36-405(B) and that is within 30 miles of the abortion clinic by road, as defined in A.R.S. § 17-451, remains on the abortion clinic's premises until all patients who received a surgical abortion are stable and ready to leave the recovery room; and
- 3-4. A physician, a nurse, a registered nurse practitioner, a physician assistant, or, if a physician is able to provide direct supervision as defined in A.R.S. § 32-1401 or A.R.S. § 32-1800 as applicable, a medical assistant under the direct supervision of the physician:
  - a. Monitors each patient during the patient's recovery following the abortion; and
  - b. Remains in the ~~facility~~ abortion clinic until each patient is discharged by a physician.

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**R9-10-1507. Patient Rights**

A licensee shall ensure that a patient is afforded the following rights, and is informed of these rights:

1. To refuse treatment, or withdraw consent for treatment;
2. To have medical records kept confidential; and
3. To be informed of:
  - a. Billing procedures and financial liability before abortion services are provided;
  - b. Proposed medical or surgical procedures, associated risks, possible complications, and alternatives;
  - c. Counseling services that are provided in the physical facilities; and
  - d. ~~If an ultrasound is performed the,~~ The right to review the ultrasound results with a physician, a physician assistant, a registered nurse practitioner, or a registered nurse before the abortion procedure.

**R9-10-1508. Abortion Procedures**

**A.** A medical director shall ensure that a medical evaluation of a patient is conducted before ~~performing an~~ the patient's abortion is performed and that includes:

1. A medical history including:
  - a. Allergies to medications, antiseptic solutions, or latex;
  - b. Obstetrical and gynecological history;
  - c. Past surgeries;
  - d. Medication the patient is currently taking; and
  - e. Other medical conditions;
2. A physical examination performed by a physician that includes a bimanual examination to estimate uterine size and palpation of adnexa; and
3. The following laboratory tests:
  - a. A urine or blood test to determine pregnancy ~~if an ultrasound examination is not performed;~~
  - b. Rh typing unless the patient provides written documentation of blood type acceptable to the physician;
  - c. Anemia screening; and
  - d. Other laboratory tests recommended by the physician or medical director on the basis of the physical examination.

**B.** If the medical evaluation indicates a patient is Rh negative, a medical director shall ensure that:

1. The patient receives information from a physician on this condition;
2. The patient is offered RhO(d) immune globulin within 72 hours after the abortion procedure;
3. If a patient refuses RhO(d) immune globulin, the patient signs and dates a form acknowledging the patient's condition and refusing the RhO(d) immune globulin;
4. The form in subsection (B)(3) is maintained in the patient's medical record; and
5. If a patient refuses RhO(d) immune globulin or if a patient refuses to sign and date an acknowledgment and refusal form, the physician documents the patient's refusal in the patient's medical record.

**C.** A physician estimates the gestational age of the fetus, and records the estimated age in the patient's medical record. The estimated age is based upon:

1. Ultrasound measurements of the biparietal diameter, length of femur, abdominal circumference, visible pregnancy sac, or crown-rump length or a combination of these; or
2. The date of the last menstrual period or the date of fertilization and a bimanual examination of the patient.

**D.** ~~If a physical examination or other information obtained from the patient or laboratory tests indicates the gestational age of the fetus is greater than 12 weeks, a~~ A medical director shall ensure that:

1. An ultrasound ~~of a patient~~ is performed by an individual who meets the requirements in R9-10-1505(3);
2. An ultrasound estimate of gestational age of a fetus is performed using methods and tables or charts published in a nationally recognized medical journal;
3. An original patient ultrasound print is:
  - a. Interpreted by a physician; and
  - b. Maintained in the patient's medical record in either electronic or paper form; and
4. If requested by the patient, the ultrasound is reviewed with the patient by a physician, ~~a~~ physician assistant, ~~a~~ registered nurse practitioner, or ~~a~~ registered nurse.

**E.** A medical director shall ensure that before an abortion is performed on a patient:

1. Written consent is signed and dated by the patient or the patient's ~~representative~~ legal guardian; and
2. Information is provided to the patient on the abortion procedure including alternatives, risks, and potential complications.

**F.** A medical director shall ensure that an abortion is performed according to the abortion clinic's policies and procedures and this Article.

**G.** A medical director shall ensure that any medication, drug, or substance used to induce an abortion is administered in compliance with the protocol authorized by the United States Food and Drug Administration and that is outlined in the final printing labeling instructions for that medication, drug, or substance.

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**~~G.H.~~** A medical director shall ensure that:

1. Patient care staff monitor the patient's vital signs throughout ~~the~~ an abortion procedure to ensure the patient's health and safety;
2. Intravenous access is established and maintained on a patient undergoing an abortion after the first trimester unless the physician determines that establishing intravenous access is not appropriate for the particular patient and documents that fact in the patient's medical record; and
3. If a viable fetus shows signs of life:
  - a. Resuscitative measures are used to support life;
  - b. The viable fetus is transferred as required in R9-10-1509; and
  - c. Resuscitative measures and the transfer are documented.

**~~H.I.~~** A medical director shall ensure that following the abortion procedure:

1. A patient's vital signs and bleeding are monitored by a physician, ~~a~~ nurse, ~~a~~ registered nurse practitioner, ~~a~~ physician assistant, or, if a physician is able to provide direct supervision as defined in A.R.S. § 32-1401 or A.R.S. § 32-1800, as applicable, a medical assistant under the direct supervision of the physician to ensure the patient's health and safety; and
2. A patient remains in the recovery room or recovery area until a physician, ~~a~~ physician assistant, ~~a~~ registered nurse practitioner or ~~a~~ nurse examines the patient and determines that the patient's medical condition is stable and the patient is ready to leave the recovery room or recovery area.

**~~I.J.~~** A medical director shall ensure that follow-up care includes:

1. With a patient's consent, a telephone call to the patient by a member of the patient care staff, except a surgical assistant, within 24 hours ~~of~~ after the patient's discharge following a surgical abortion to assess the patient's recovery. If the patient care staff is unable to speak with the patient, for any reason, the attempt to contact the patient is documented in the patient's medical record; ~~and~~
2. ~~A~~ Following a surgical abortion, a follow-up visit offered and scheduled, if requested, no more than 21 days after the abortion. The follow-up visit shall include:
  - a. A physical examination;
  - b. A review of all laboratory tests as required in R9-10-1508(A)(3); and
  - c. A urine pregnancy test; and
3. Following a medication abortion, a follow-up visit offered and scheduled between seven and 21 days after the initial dose of a substance used to induce an abortion. The follow-up visit shall include:
  - a. A urine pregnancy test; and
  - b. An assessment of the degree of bleeding.

**~~J.K.~~** If a continuing pregnancy is suspected as a result of the follow-up visit required in subsection ~~(H)(2)~~ (J)(2) or (J)(3), a physician who performs abortions shall be consulted.

**R9-10-1509. Patient Transfer and Discharge**

**A.** A medical director shall ensure that:

1. A patient is transferred to a hospital for an emergency involving the patient;
2. A viable fetus requiring emergency care is transferred to a hospital;
3. A patient transfer is documented in the patient's medical record; and
4. Documentation of a medical evaluation, treatment given, and laboratory; and diagnostic information is transferred with a patient.

**B.** A medical director shall ensure that before a patient is discharged:

1. A physician signs the patient's discharge order; and
2. A patient receives ~~written information~~ follow-up instructions at discharge that ~~includes~~ include:
  - a. Signs of possible complications;
  - b. When to access medical ~~care~~ services in response to complications;
  - c. A telephone number of an individual or entity to contact for medical emergencies;
  - d. ~~Instructions~~ Information and precautions for resuming vaginal intercourse after the abortion; and
  - e. ~~Instructions~~ Information specific to the patient's abortion or condition.

**R9-10-1510. Medications and Controlled Substances**

A medical director shall ensure that:

1. The abortion clinic complies with the requirements for medications and controlled substances in A.R.S. Title 32, Chapter 18, and A.R.S. Title 36, Chapter 27;
2. A medication is administered in compliance with an order from a physician, physician assistant, registered nurse practitioner, or as otherwise provided by law;
3. A medication is administered to a patient by a physician or as otherwise provided by law;
4. Medications and controlled substances are maintained in a locked area in the physical facilities;
5. Only personnel designated by ~~in the abortion clinic's~~ policies and procedures have access to the locked area contain-



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- ing the medications and controlled substances;
6. Expired, mislabeled, or unusable medications and controlled substances are disposed of according to ~~the abortion clinic's~~ policies and procedures;
7. ~~Medication errors and adverse reactions~~ A medication error or an adverse reaction, including any actions taken in response to the medication ~~errors error~~ or adverse ~~reactions-reaction~~, ~~are~~ is immediately reported to the medical director and licensee, and recorded in the patient's medical record;
8. Medication information is maintained in a patient's medical record and contains:
  - a. The patient's name, age, and weight;
  - b. The medications the patient is currently taking; and
  - c. Allergies or sensitivities to medications, antiseptic solutions, or latex; and
9. If medication is administered to a patient, the following are documented in the patient's medical record:
  - a. The date and time of administration;
  - b. The name, strength, dosage form, amount of medication, and route of administration; and
  - c. The identification and signature of the individual administering the medication.

**R9-10-1511. Medical Records**

**A.** A licensee shall ensure that:

1. A medical record is established and maintained for a patient that contains:
  - a. Patient identification including:
    - i. The patient's name, address, and date of birth;
    - ii. The designated ~~patient~~ patient's representative, if applicable; and
    - iii. The name and telephone number of an individual to contact in an emergency;
  - b. The patient's medical history required in R9-10-1508(A)(1);
  - c. The patient's physical examination required in R9-10-1508(A)(2);
  - d. The laboratory test results required in R9-10-1508(A)(3);
  - e. The physician's estimated gestational age of the fetus required in R9-10-1508(C);
  - f. The ultrasound results, ~~if applicable~~, including the original print, ~~as~~ required in R9-10-1508(D);
  - g. Each consent form signed by the patient or the patient's ~~representative~~ legal guardian;
  - h. ~~A record of all orders~~ Orders issued by a physician, physician assistant or registered nurse practitioner;
  - i. A record of ~~all~~ medical services, nursing services, and health-related services provided to the patient; and
  - j. The patient's medication information;
2. A medical record is accessible only to the Department or personnel authorized by ~~the abortion clinic's~~ policies and procedures;
3. Medical record information is confidential and released only with the written informed consent of a patient or the patient's representative or as otherwise permitted by law;
4. A medical record is protected from loss, damage, or unauthorized use and is maintained and accessible for seven years ~~from~~ after the date of an adult patient's discharge or if the patient is a child, either for at least three years after the child's 18th birthday or for at least seven years after the patient's discharge, whichever date occurs last;
5. A medical record is maintained at the abortion clinic for at least six months ~~from~~ after the date of the patient's discharge; and
6. Vital records and vital statistics are retained according to A.R.S. § 36-343; and
7. ~~If an abortion clinic ceases operations, the Department is notified in writing, not less than 30 days before ceasing operations, of the location of the abortion clinic's medical records.~~

**B.** A licensee shall comply with Department requests for access to or copies of patient medical records as follows:

1. Subject to the redaction permitted in subsection (B)(5), for patient medical records requested for review in connection with a compliance inspection, the licensee shall provide the Department with the following patient medical records related to medical services associated with an abortion, including any follow-up visits to the ~~facility~~ abortion clinic in connection with the abortion:
  - a. Patient identification including:
    - i. The patient's name, address, and date of birth;
    - ii. The designated ~~patient~~ patient's representative, if applicable; and
    - iii. The name and telephone number of an individual to contact in an emergency;
  - b. The patient's medical history required in R9-10-1508(A)(1);
  - c. The patient's physical examination required in R9-10-1508(A)(2);
  - d. The laboratory test results required in R9-10-1508(A)(3);
  - e. The physician's estimated gestational age of the fetus required in R9-10-1508(C);
  - f. The ultrasound results, ~~if applicable~~, including the original print ~~as~~ required in R9-10-1508(D);
  - g. Each consent form signed by the patient or the patient's representative;
  - h. ~~A record of all orders~~ Orders issued by a physician, physician assistant, or registered nurse practitioner;
  - i. A record of ~~all~~ medical services, nursing services, and health-related services provided to the patient; and

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- j. The patient's medication information.
2. For patient medical records requested for review in connection with an initial licensing or compliance inspection, the licensee is not required to produce for review by the Department any patient medical records created or prepared by a referring physician or any of that referring physician's medical staff.
3. The licensee is not required to provide patient medical records regarding medical services associated with an abortion that occurred before:
  - a. The effective date of these rules, or
  - b. A previous licensing or compliance inspection of the abortion clinic.
4. The patient medical records may be provided to the Department in either paper or in an electronic format that is acceptable to the Department.
5. When access to or copies of patient medical records are requested from a licensee by the Department, the licensee shall redact only personally identifiable patient information from the patient medical records before the disclosure of the patient medical records to the Department, except as provided in subsection (B)(8).
6. For patient medical records requested for review in connection with an initial licensing or compliance inspection, the licensee shall provide the redacted copies of the patient medical records to the Department within two business days of the Department's request for the redacted medical records if the total number of patients for whom patient medical records are requested by the Department is from one to ten patients, unless otherwise agreed to by the Department and the licensee. The time within which the licensee shall produce redacted records to the Department shall be increased by two business days for each additional five patients for whom patient medical records are requested by the Department, unless otherwise agreed to by the Department and the licensee.
7. Upon request by the Department, in addition to redacting only personally identifiable patient information, the licensee shall code the requested patient medical records by a means that allows the Department to track all patient medical records related to a specific patient without the personally identifiable patient information.
8. The Department shall have access to or copies of unredacted patient medical records only ~~pursuant~~ according to an administrative search warrant specifically authorizing the disclosure of unredacted patient medical records by the licensee.
9. If the Department obtains copies of unredacted patient medical records, the Department shall:
  - a. Allow the examination and use of the unredacted patient medical records only by those Department employees who need access to the patient medical records to fulfill their investigative responsibilities and duties;
  - b. Maintain all unredacted patient medical records in a locked drawer, cabinet, or file or in a password-protected electronic file with access to the secured drawer, cabinet, or file limited to those individuals who have access to the patient medical records ~~pursuant~~ according to subsection (B)(9)(a);
  - c. Destroy all unredacted patient medical records at the termination of the Department's investigation or at the termination of any administrative or legal action that is taken by the Department as the result of the Department's investigation, whichever is later;
  - d. If the unredacted patient medical records are filed with a court or other judicial body, including any administrative law judge or panel, file the records only under seal; and
  - e. Prevent access to the unredacted records by anyone except as provided in subsection (B)(9)(a) or subsection (B)(9)(d).
- C. A medical director shall ensure that only personnel authorized by ~~an abortion clinic's~~ an abortion clinic's policies and procedures, records or signs an entry in a medical record and:
  1. An entry in a medical record is dated and legible;
  2. An entry is authenticated by:
    - a. A written signature;
    - b. An individual's initials if the individual's written signature already appears in the medical record;
    - c. A rubber-stamp signature; or
    - d. ~~A computer code~~ An electronic signature;
  3. An entry is not changed after it has been recorded but additional information related to an entry may be recorded in the medical record;
  4. When a verbal or telephone order is entered in the medical record, the entry is authenticated within 21 days by the individual who issued the order;
  5. If a rubber-stamp signature or ~~a computer code~~ an electronic signature is used:
    - a. An individual's rubber stamp or ~~computer code~~ electronic signature is not used by another individual;
    - b. The individual who uses a rubber stamp or ~~computer code~~ electronic signature signs a statement that the individual is responsible for the use of the rubber stamp or the ~~computer code~~ electronic signature; and
    - c. The signed statement is included in the individual's personnel record; and
  6. If an abortion clinic maintains medical records electronically, the medical director shall ensure the date and time of an entry is recorded by the computer's internal clock.
- D. As required by A.R.S. § 36-449.03(I), the Department shall not release any personally identifiable patient or physician

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information.

**R9-10-1512. Environmental and Safety Standards**

A licensee shall ensure that:

1. Physical facilities:
  - a. Provide lighting and ventilation to ensure the health and safety of a patient;
  - b. Are maintained in a clean condition;
  - c. Are free from a condition or situation that may cause a patient to suffer physical injury;
  - d. Are maintained free from insects and vermin; and
  - e. Are smoke-free;
2. A warning notice is placed at the entrance to a room or area where oxygen is in use;
3. Soiled linen and clothing are kept:
  - a. ~~in~~ In a covered container, ~~and in a~~
  - b. ~~separate area~~ Separate from clean linen and clothing;
4. Personnel wash hands after each direct patient contact and after handling soiled linen, soiled clothing, or biohazardous medical waste;
5. A written emergency plan is ~~developed~~ established, documented, and implemented that includes procedures for protecting the health and safety of patients and other individuals in a fire, natural disaster, loss of electrical power, or threat or incidence of violence; and
6. An evacuation drill is conducted at least once every six months that includes all personnel in the physical facilities the day of the evacuation drill. Documentation of the evacuation drill is maintained in the physical facilities for one year ~~from~~ after the date of the evacuation drill and includes:
  - a. The date and time of the evacuation drill; and
  - b. The names of personnel participating in the evacuation drill.

**R9-10-1513. Equipment Standards**

A licensee shall ensure that:

1. Equipment and supplies are maintained in a quantity sufficient to meet the needs of ~~all~~ patients present in the abortion clinic;
2. Equipment to monitor vital signs is in each room in which an abortion is performed;
3. A surgical or gynecologic examination table is used for an abortion;
4. The following equipment and supplies are ~~provided~~ available in the abortion clinic:
  - a. Equipment to measure blood pressure;
  - b. A stethoscope;
  - c. A scale for weighing a patient;
  - d. Supplies for obtaining specimens; and cultures and ~~other~~ for laboratory tests; and
  - e. Equipment and supplies for use in a medical emergency including:
    - i. Ventilatory assistance equipment;
    - ii. Oxygen source;
    - iii. Suction apparatus; and
    - iv. Intravenous fluid equipment and supplies; and
  - f. Ultrasound equipment;
5. In addition to the requirements in subsection (4), the following equipment is available for an abortion procedure performed after the first trimester:
  - a. ~~Ultrasound equipment;~~
  - b. a. Drugs to support cardiopulmonary function; and
  - c. b. Equipment to monitor cardiopulmonary status;
6. Equipment and supplies are clean and, if applicable, sterile, ~~if applicable,~~ before each use;
7. Equipment required in this Section is maintained in working order, tested and calibrated at least once every 12 months or according to the manufacturer's recommendations, and used according to the manufacturer's recommendations; and
8. Documentation of each equipment test, calibration, and repair is maintained in the physical facilities for one year ~~from~~ after the date of the testing, calibration, or repair and provided to the Department for review within two hours ~~from the time~~ after the Department requests the documentation.

**R9-10-1514. Physical Facilities**

- A. A licensee shall ensure that an abortion clinic complies with all local building codes, ordinances, fire codes, and zoning requirements. If there are no local building codes, ordinances, fire codes, or zoning requirements, the abortion clinic shall comply with the applicable codes and standards incorporated by reference in A.A.C. R9-1-412 that were in effect on the date the abortion clinic's architectural plans and specifications were submitted to the Department for approval.
- B. A licensee shall ensure that an abortion clinic provides areas or rooms:

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1. That provide privacy for:
    - a. A patient's interview, medical evaluation, and counseling;
    - b. A patient to dress; and
    - c. Performing an abortion procedure;
  2. For personnel to dress;
  3. With a sink ~~in working order~~ and a flushable toilet in working order;
  4. For cleaning and sterilizing equipment and supplies;
  5. For storing medical records;
  6. For storing equipment and supplies;
  7. For hand washing before the abortion procedure; and
  8. For a patient recovering after an abortion.
- C. A licensee shall ensure that an abortion clinic has an emergency exit to accommodate a stretcher or gurney.

**R9-10-1515. Enforcement**

- A.** For an abortion clinic that is not in substantial compliance or that is in substantial compliance but refuses to carry out a plan of correction acceptable to the Department, the Department may:
1. Assess a civil penalty according to A.R.S. § 36-431.01.
  2. Impose an intermediate sanction according to A.R.S. § 36-427.
  3. Suspend or revoke a license according to A.R.S. § 36-427.
  4. Deny a license, or
  5. Bring an action for an injunction according to A.R.S. § 36-430.
- B.** In determining the appropriate enforcement action, the Department shall consider the threat to the health, safety, and welfare of the abortion clinic's patients or the general public, including:
1. Whether the abortion clinic has repeated violations of statutes or rules;
  2. Whether the abortion clinic has engaged in a pattern of noncompliance; and
  3. The type, severity, and number of violations.